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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/690,973	10/18/2000	Spiridon Spircas	MPCI-0024	4370

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04/23/2002

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EXAMINER

WARE, TODD

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/23/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/690,973

Applicant(s)

SPIREAS, SPIRIDON

Examiner

Todd D Ware

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-89 is/are pending in the application.
- 4a) Of the above claim(s) 24-77 and 80-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23, 78 and 79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Receipt of declaration filed 5-10-01, information disclosure statement filed 1-29-01, request for extension of time (granted) filed 5-10-01, and small entity status filed 11-21-00, and election filed 2-1-02 is acknowledged.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-23 and 78-79 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that since Groups II and III are drawn to related subject matter and Groups I and II are classified in the same class and subclass, no serious burden would be imposed upon the Examiner. This is not found persuasive because a) Group II is classified separately, showing that this subject matter has attained recognition in the art as a separate subject for inventive effort and also a separate field of search and b) Groups I, II, and III require a different field of search, in that the search for one of the distinct subjects is different for another (i.e. Group I avoids moisture induced degradation through preparation under low compression and Group II avoids moisture induced degradation through incorporation of oil and Group II avoids moisture induced degradation through incorporation of hydrophobic powder. Thus, serious burden is placed upon the Examiner since each of the groups requires a different field of search.

The requirement is still deemed proper and is therefore made FINAL.

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2. Claims 24-77 and 80-89 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8, 19, 78, and 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 19 do not use Markush language and the claim is indefinite because it is unclear whether all the ingredients are excipients in the formulation or if each ingredient is a separate member of a group of excipients. Amendment with "selected from the group consisting of" would overcome this rejection. See MPEP 2173.05(h). For purposes of examination, the claims are examined as such.

Claim 78 recites the limitation "the hormone" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 79 recites the limitation "the levothyroxine" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2, 4-8, 10-13, 15-19, 21-23, and 78-79 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chen et al (5,225,204; hereafter '204).

'204 discloses levothyroxine capsule powder formulations with hydroxypropyl methylcellulose (abstract; C 3, L 28-32, 68; C 5, L 1-29, L 52-54; Example 1 & 3; claims).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-2, 4-13, 15-23, and 78-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (5,225,204; hereafter '204).

'204 teaches levothyroxine capsule powder formulations with hydroxypropyl methylcellulose (abstract; C 3, L 28-32, 68; C 5, L 1-29, L 52-54; Example 1 & 3; claims).

'204 does not specifically state that the residual moisture content should be less than about 10% by weight, however it would have been obvious to one skilled in the art at

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the time of the invention with the motivation of maximizing stability of the levothyroxin and the expectation that levothyroxin degrades rapidly under conditions of high humidity (C 1, L 32-35; C 2, L 32-35; C 3, L 10-15; C 5, L 52-54).

10. Claims 1-2, 4-13, 15-23, and 78-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (5,225,204; hereafter '204) in view of Mitra (5,955,105; hereafter '105).

'204 is relied upon for all that it teaches as stated previously. '204 does not specifically teach that the residual moisture content should be less than about 10% by weight.

'105 is relied upon for teaching levothyroxine formulations having a moisture content less than 4.5% provide maximum stability of levothyroxine.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '204 and '105 with the motivation of providing maximum stability of the formulation.

11. Claims 1-2, 4-13, 15-23, and 78-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (5,225,204; hereafter '204) in view of Sarkar (4,001,211; hereafter '211) or Chen et al (5,225,204; hereafter '204) in view of Yamamoto et al (5,756,123; hereafter '123).

'105 is relied upon for all that it teaches as stated previously. '105 does not teach the limitations where the capsule shell is formed of hydroxypropyl methylcellulose.

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'211 and '123 both teach capsule shells comprising hydroxypropyl methylcellulose

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to use capsule shells formed of hydroxypropyl methylcellulose in the formulation of '105 with the motivation of providing capsules that are stable under humid conditions and that do not lose their ability to degrade under particular conditions.

12. Claims 1, 5-12, 16-23, and 78-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Mitra (5,955,105; hereafter '105) in view of Schor et al (4,389,393; hereafter '393) or Mitra (5,955,105; hereafter '105) in view of Maish et al (4,983,399; hereafter '399).

'105 teaches levothyroxine formulations having a moisture content less than 4.5% provide maximum stability of levothyroxine. '105 doesn't specifically teach the instant limitations requiring no compression greater than 2,000 psi/g, 5,000 psi/g or 10,000 psi/g.

'393 and '399 both teach that formulations compressed at 2,000 psi/g, 5,000 psi/g or 10,000 psi/g are well-known in the art.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to compress the formulations of '105 at these pressures with the motivation of obtaining a tablet with a desired hardness, friability, and disintegration time.

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Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
April 16, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600